California Department of Health Services
Medi-Cal Drug Rebate/Dispute Resolution
Frequently Asked Questions

Contained in this document is a listing of FAQ's for the Medi-Cal drug rebate program. For your convenience some quick links have been provided to the more commonly asked questions

California Department of Health Services

Revised April 19, 2006

Medi-Cal Drug Rebate/Dispute Resolution
Frequently Asked Questions (FAQ's)

Q: What is California's reimbursement rate?

Medi-Cal reimburses pharmacies billing for drugs at the Estimated Acquisition Cost (EAC) plus a dispensing fee.

From about 1989 until November 30, 2002, Medi-Cal calculated EAC as the lowest of:

- AWP minus 5% for most drugs
- Direct price for certain manufacturers
- Federal Upper Limit (FUL) price for certain drugs
- State Maximum Allowable Ingredient Cost (MAIC) price for certain drugs
- The pharmacy's charge

Legislation was enacted December 1, 2002 for AWP-10%, but for rebate purposes it became effective the first day of the month of the following quarter (January 1, 2003). During this time Medi-Cal calculated EAC as the lowest of:

- AWP minus 10%
- Federal Upper Limit (FUL) price for certain drugs
- State Maximum Allowable Ingredient Cost (MAIC) price for certain drugs
- The pharmacy's charge

Legislation was enacted September 1, 2004 for AWP-17%, but for rebate purposes it became effective the first day of the month of the following quarter (October 1, 2004). The rate is now the lowest of:

- AWP-17%
- Selling Price (Selling price will be based on Average Sales Price)
- MAIC
- FUL
- Provider charge

Q: What is California's pharmaceutical dispensing fee?

Effective October 1, 2004 (4Q04 Invoices) California's dispensing fee will be $7.25 per claim, except that claims with a Place of Service Code of 4, C, F, G, H, I, M, or N, which indicate **L**ong **T**erm **C**are Claims, will be reimbursed an $8.00 dispensing fee per claim. The .10-cent per claim reduction will also be eliminated.
From 1986 until August 31, 2004 California's pharmaceutical dispensing fee =$4.05.

Q: ***What is California's rate reduction history?***

From 1995 to September 2004 California reduced the amount that it reimburses each claim by the following amounts for the following periods. Manufacturers may want to take these amounts into consideration when setting outliers in drug rebate claims review.

Rate Reduction History

- Jan 1, 1995 - 50-cent reduction per claim
- Jan 1, 2000 - 25-cent reduction per claim
- July 1, 2002 - 10-cent reduction per claim
- Oct 1, 2002 - 50-cent reduction per claim, except **LTC** claims (using the place of service codes 4, C, F, G, H, I, M, or N) have a 10-cent reduction
- July 1, 2004 - 10-cent reduction per claim
- Sep 1, 2004 - no reduction per claim

Q: What is California's maximum number of days supply when dispensing drugs?

California has a 100-day maximum days supply for most drugs. This is different from other states that may only have a 30-day maximum dispensing practice; however, most claims (75 to 80% are for 30 days or less).

Q: Why does Medi-Cal reimburse Kaiser at such a low rate?

The reimbursed dollars are not always the best indicator of what was actually dispensed. Other Health Coverage or Third Party Liability (TPL) information may not always be entered as part of the Medi-Cal claim. It is normal to see Kaiser Permanente claims for their fee-for-service Medi-Cal patients being reimbursed for a co-pay of $5 - $30 with no TPL data. For that reason, most Kaiser claims are correct and the units are correctly invoiced for rebates.

Q: Can normal prescription practices vary and/or be overridden?

Yes. A Treatment Authorization Request (TAR) can be used to override normal prescription practices (i.e. prescriptions in excess of six prescriptions at a time for one beneficiary, quantities larger than usual dispensing quantities, drugs not on the List of Contract Drugs, etc.)

Q: Why do I need to submit Average Manufacturers Price (AMP) data on certain NDCs?

Only those labelers who have agreed to pay California a state supplemental rebate based on AMP need to provide AMP data. Because your labeler signed one or more AMP- based supplemental rebate contract(s) for certain NDC(s), you must send AMP data updates quarterly to California. Medi-Cal uses the AMP to calculate the supplemental rebate due.

Q: When is Average Manufacturer Pricing (AMP) data due in California?

AMP must be submitted to the California Department of Health Services (DHS) fiscal intermediary, Electronic Data Systems (EDS), prior to the CMS deadline. The CMS deadline is 30 days after the end of the quarter.

Q: What happens if I don't turn in the AMP data timely?

Labelers should be aware that if they do not submit their data for two consecutive quarters, their California Supplemental AMP contract may either be terminated or not renewed when the current contract expires. Without an active contract, DHS would make the labeler's drug available only through prior authorization.

Q: Where do I submit the AMP data?

AMP data is submitted to the DHS Fiscal Intermediary, EDS, by formatted diskette or email.

Q: How do I submit the AMP data to EDS?

The DHS AMP coordinator will make sure all labeler AMP contacts have received the "AMP Coordinator reminder email letter" and any "revised" AMP data submission instructions two weeks prior to the CMS deadline. The address to submit AMP is included in the letter, and is also noted here:

Electronic Data Systems (EDS)
Drug Rebate Unit
Attention: Rebate Unit, Supervisor
3215 Prospect Park Drive
Rancho Cordova, CA 95670

Q: What if my AMP/RPU data changes?

If a labeler makes a change in AMP data, they need to submit that updated data to CMS, which in turn will notify DHS, by tape, in the following quarters. DHS' rebate system will then adjust the labelers account status on the rebate accounting system and report the new amounts on the next invoice.
The labeler's report AMP to the states on a quarterly basis. AMP is loaded into the **R**ebate and **A**ccounting **I**nformation **S**ystem (RAIS) once per quarter, so any changes will need to be reported to DHS the following quarter.

Q: What if I have problems with my AMP data?

If there are any problematic submissions, EDS normally will contact the labeler for resubmission and log this information. If a labeler is chronically late and/or inaccurate, then a detailed history of the labeler's data submission compliance will be given to the labeler's government representative. Consistently flawed data submissions may result in the Department terminating the rebate contract.

Q: What if I can't find a copy of my contract?

Labelers must submit a written request, on the labeler's letterhead to DHS. The request can be faxed to DHS at 916-552-9563 or mailed to this address:

California Department of Health Services
Pharmacy Policy & Contracting Section,
Attn: Chief
P.O. Box 997417, MS 4604
Sacramento, CA 95899-7417

Q: What qualifies a Provider as a Public Health Services (PHS) entity in California and eligible for 340B pricing?

The 340B PHS program is a federal program that allows eligible entities to buy drugs at very low prices. The provider must be a Disproportionate Share Hospital (DSH), Federally Qualified Health Center (FQHC), or Indian Health Center. Additional information about the 340B PHS Program can be found at: http://www.hrsa.gov/opa/introduction.htm.
The provider must pass the discount on to Medi-Cal by only billing actual acquisition cost plus the $4.05 dispensing fee. There are no rebates on drugs PHS facilities purchase through a PHS contract.
Some examples of PHS providers-

- County Hospitals
- University of California Hospitals

A complete listing can be found here: http://opanet.hrsa.gov/opa/CE/CEExtract.aspx .

Note: Although a provider may have a PHS contract, the provider may not have purchased the drug through that contract. In order to verify that, we request that labelers send us the pertinent chargeback data for the PHS facilities, to verify the units are not rebateable.

Q: What are the Federal and State Laws regarding the Drug Rebate Program in California?

Federal Law

- **Social Security Act Section 1927** ***[42 U.S.C. 1396r-8]*** **(a)-** Federal legislation related to the Medicaid (AKA Medi-Cal in California) Drug Rebate Program. For Social Security online, go to http://www.socialsecurity.gov/OP_Home/ssact/title19/1927.htm.

State Law

- **Welfare and Institutions (W&I) Code Section 14105-** Relates to Medi-Cal Drug Rebate Program. To view the web site, go to: http://www.leginfo.ca.gov/index.html click the California Law button, select Welfare and Institutions Code, and enter a law section in the search engine field. For example, enter 14105.35 to access that section of law. For Assembly or Senate Bills select Bill Information.
    - **Assembly Bill 2377, 1994-** Relates to 10% State Supplemental Rebates. (Effective date of 7/1/94 and a sunset date of 7/1/96)
    - **Senate Bill 391, 1997-** Amended Welfare & Institutions Code 14105.33-Relates to State Supplemental interest and penalty. (Effective date 10/1/97) still in effect

- **Senate Bill 485, 1992-** Amended Welfare & Institutions Code 14105.33-Relates to State Supplemental Rebates. (Effective dates 7/1/92 through 9/30/93)

Q: What types of programs are involved in the California Department of Health Services Drug Rebate Program?

The following programs are involved in the CDHS Drug Rebate Program-

- Medi-Cal
- Medi-Cal Supplemental
- FPACT
- Medical Claims (HCPCS)
- FPACT Medical Claims (HCPCS)
- Compounds billed with HCPCS
- COHS
- COHS Supplemental
- CMSP
- CCS/GHPP
- Blood Factors

Details on these plans are noted below.

Medi-Cal

Q: What are "Medi-Cal" rebates?

"Medi-Cal" rebates are California's term for the federal rebate program. Medi-Cal is California's Medicaid health care program. Invoicing for drug rebates under this program began for 1st quarter 1991 and continues to the present.

Medi-Cal Supplemental

Q: What are "Medi-Cal supplemental" rebates?

"Medi-Cal supplemental" rebates are defined as rebates labelers have agreed to pay the state in addition to the federal rebates. This program began in 1991 and is a state supplemental rebate program. DHS puts drugs for which labelers have agreed to pay a supplemental rebate on a "List of Contract Drugs". Drugs on the "List" are generally not subject to the prior authorization required for many drugs.

Negotiating supplemental contracts by DHS Pharmacists is an ongoing process as most contracts are for three years.

Other Supplemental programs were-

- **Senate Bill 485, 1992** (Effective dates 7/1/92 through 9/30/93)

Required DHS to obtain supplemental rebates during this period. These rebates were in addition to any rebates provided to the California Medicaid program under the terms of the CMS rebate agreement. Any manufacturer refusing to provide these supplemental rebates was put on prior authorization status for all of their drugs, (each prescription would have to be approved on a case-by-case basis with a TAR). Any manufacturer who was providing a rebate for a product in excess of the applicable amount indicated as supplemental did not have to provide an additional supplemental rebate for that product.

- **Assembly Bill 2377, 1994** (Effective date of 7/1/94 and a sunset date of 7/1/96)

Added Welfare & Institutions Code Section 14105.335 required pharmaceutical manufacturers to pay a supplemental rebate, in addition to the federal rebate, for each of their drugs reimbursed by Medi-Cal equal to 10% of AMP.

This provision required the Department to place the drug products of any manufacturer refusing to provide the 10% supplemental rebates on prior authorization status. Drugs that were added to the Medi-Cal List of Contract Drugs pursuant to Welfare & Institutions Code Section 14105.43 or 14133.2 (AIDS drugs and cancer drugs) did not require supplemental rebates

Note: The sunset date of 7/1/96 was later extended to 12/31/96 through a contract document. The original contract and the extended contract were administered via an "All Manufacturers" letter.

- **Assembly Bill 3483, 1996** (Effective date 7/22/96 with and sunset date of 1/1/97)
- **Senate Bill 391 Solis, 1997** (Effective date 10/1/97) still in effect

Q: Are supplemental rebates subject to interest charges?

Yes, the Welfare & Institutions Code 14105.33 was amended to impose interest and interest penalties on State Supplemental Rebates, beginning with the 4th quarter of 1997.

- If a quarter's supplemental payment is not received within 38 days from the date the invoice is postmarked, interest calculated at the CMS rate (Weekly T-bill rate) is due.
- If a quarter's supplemental payment is not received within 69 days of the invoice postmark date, an interest penalty of 10 percentage points must be added to the weekly T-bill rate under the CMS interest formula. The interest and the 10% penalty continue to accrue until the day payment is postmarked to us.
- If a manufacturer made a supplemental overpayment as a result of a dispute resolution, the state owes interest for payments made 38 days after the date of dispute resolution.

Q: What does the supplemental rebate legislation mean to drug rebates?

3q1992 through 3q1993 - Supplemental rebates were owed pursuant to Senate Bill 485 for each of labelers' NDCs. The rebate amount calculation varies depending on the type of drug (single-source, innovator multi-source or non-innovator multiple-source). If an additional existing

negotiated supplemental contract existed for any of their NDCs, a combination of the two was owed.

3q1994 through 4q1996 - Supplemental rebates were owed pursuant to Assembly Bill 2377 for each of their NDCs. The rebate amount calculation was 10% of AMP. For manufacturers with separately negotiated supplemental contracts the combination of the two percentages should come up to the 10%. If the negotiated supplemental contract was for more than the 10%, no additional rebate was owed. When doing Supplemental dispute resolution activity, DHS analysts verify that the 10% Supplemental RPU was calculated and paid correctly.

Types of supplemental contracts – As noted in the above, these contracts were either mandated by legislation or are the result of negotiations between the labeler and the state.

Q: What are the rebates based on?

Terms of contracts can be AMP-based or Net Cost or a combination thereof.

Q: Do I get a separate invoice for supplemental rebates?

Yes. From 4th quarter 2001, EDS has invoiced Medi-Cal and Medi-Cal Supplemental on separate invoices. Previously, labelers would calculate the supplemental rebate based on the Medi-Cal invoiced utilization and the negotiated terms. They would basically multiply the Medi-Cal units by whatever RPU they had negotiated with the state, and send this amount in addition to their Medi-Cal rebate.

From 4th quarter 2001 forward, DHS uses the most recent AMP submitted by the labeler or the Net Cost, as applicable needed, to provide the labeler with an estimated invoice dollar amount due.

FPACT

What is "FPACT"?

FPACT is the **F**amily **P**lanning, **A**ccess, **C**are, and **T**reatment program incorporated into Medi-Cal via a Federal waiver.

FPACT allows for federally matched funds to be used for reproductive health services for medically indigent females.

Prior to December 1, 1999, FPACT was a State-only program. As the result of the approved Federal waiver, the scope of the State-only program changed and put FPACT under Title XIX, thereby making FPACT utilization rebate eligible.

FPACT rebates became effective 12/1/99 causing the first invoice in 4q99 to only contain one month of utilization.

FPACT invoices continue to the present.

Q: Is FPACT utilization subject to supplemental rebates?

No. FPACT is subject only to the CMS rebate.

Physician Claims billed with HCPCS

Q: What are "HCPCS"?

HCPCS means, **H**CFA **C**ommon **P**rocedure **C**oding **S**et.

HCPCS describes the codes that physicians use to claim drugs administered in the physician's office for Medi-Cal reimbursement.

These claims are for physician-administered injections that are part of the Fee for Service utilization, but were previously not invoiced because HCPCS codes were being used instead of NDCs.

Invoices were mailed 2/4/98 retroactively for 4Q96 through 3Q97.
They are typically paper and or batch claims and the HCPCS codes are not as detailed as NDCs.

There are numerous drugs with HCPCS. However, rebates are only requested on those codes that are mapped to just one manufacturer/labeler. These single source drugs are matched to the NDC with the lowest rebate amount. If a HCPCS product is mapped to two or more labelers the product is excluded from the invoice.

The following website has a list of HCPCS X-Codes, and their corresponding drug and strength.
http://files.medi-cal.ca.gov/pubsdoco/publications/masters MTP/Part2/injectlist_m00o03o04o11.doc

FPACT HCPCS

Beginning December 1, 1999, using the same HCPCS code matching outlined above, physician administered injections dispensed under the FPACT program were invoiced for a federal rebate under a separate invoice (FPACT HCPCS).

COHS

Q: What is a "COHS"?

COHS means **C**ounty **O**rganized **H**ealth **S**ystem. Their utilization is incorporated into Medi-Cal via a Federal waiver.

Q: How many COHS are there?

There are **five** COHS' that incorporate **eight** counties.

"CalOPTIMA" – Orange County

"Central Coast Alliance for Health" – Santa Cruz and Monterey Counties

"Health Plan of San Mateo" – San Mateo County

"Partnership Health Plan" – Solano, Napa, and Yolo Counties

"Santa Barbara Health Initiative" – Santa Barbara County

Beginning with the 1st quarter of 2002, COHS claims were invoiced separately from the Medi-Cal invoice for the first time. 4th quarter 2001 data was included as Outstanding Invoice Items with the 1st quarter 2002 Invoice.

Prior to 1st quarter 2001, COHS was invoiced together with Medi-Cal.

COHS Supplemental

Any drug that has a Medi-Cal supplemental contract will also have COHS supplemental invoice.

CMSP

Q: What is the "CMSP"?

CMSP stands for **C**ounty **M**edical **S**ervices **P**rogram. CMSP is for medically indigent adults, the working poor. There were contracts with a relatively few manufacturers between 1st quarter 1991 to 2nd quarter 2001.

CCS/GHPP

California **C**hildren **S**ervices/**G**enetically **H**andicapped **P**ersons **P**rogram

Protects the parents of children under 21 from the high cost of treatment for chronic illnesses for which they have a genetic predisposition.

A few labelers contracted to pay rebates at the federal rate on the utilization of these relatively small, state-only programs. There was no supplemental payment; the contracts were only to get the federal rebate equivalent for a non-Medi-Cal population.

Invoices were valid as long as a contract was in force. All such contracts have expired.

Blood Factors

Program started in 1995.

Often called "Factor 8" or Anti-Hemophilic Factors (AHF).

DHS reimburses AHF at one percent above the invoiced amount.

CMS obtains a federal rebate; California currently does not contract for a state supplemental rebate.

The State Controllers Office performs the manual process needed to convert the HCPCS codes into NDCs to create the rebate invoice.

The Health Insurance Portability and Accountability Act (HIPAA) may change the process, substituting NDCs for HCPCS. This would permit information system changes to allow AHF to be billed online.

Q: What is the notification process if a labeler has an NDC that is terminated?

Labelers must report a TERMINATION DATE to CMS **AND** First Data Bank (FDB) in the event an NDC is terminated to ensure the Medi-Cal formulary file receives the correct update.

Q: Where should Labelers remit rebate payments?

Labelers should, within, 30 days, remit rebate payment along with the form required by the federal Health Care Financing Administration (HCFA), Form HCFA-304, Reconciliation of State Invoice (ROSI), and the second copy of the invoice to:

Department of Health Services
Accounting Section
Attn: Medi-Cal Drug Rebate Accounts Receivable
1501 Capitol Ave Ste. 71.2048
MS 1101 PO Box 997413
Sacramento, CA 95899-7413
FPACT Payments please include this information:
Attn: FPACT Drug Rebate Accounts Receivable
Account Number: 95921-580200-06

If a payment is for more than one labeler code, a separate ROSI for each labeler is required.

Please do not submit payment to any other address.

Q: What kinds of information can California offer pharmaceutical manufacturers?

California has a **R**ebate **A**ccounting **I**nformation **S**ystem that collects and processes all Medi-Cal drug claims and manufacturers drug rebate invoices. This system has all claims California has processed from 4th quarter 2001 forward. Additionally, Medi-Cal analysts can access all claims detail from a separate data warehouse from 1991 forward. This information is available to corresponding manufacturers as requested.